Yulong 玉隆塑胶厂
玉隆勝科技有限公司
YU LONG PLASTIC FACTORY / YU LONG SHENG TECHNOLOGY CO., LTD
Tel: 0755-89936600; Fax:0755-89936603; E-mail:yulin89@126.com

K102508

" 510(K) SUMMARY "

JAN 10 2011

1. Submitter's Name: *YU LONG SHENG TECHNOLOGY CO., LTD.*
   No. 76, Mingqiang Road, Pingshan Shabo Community, Pingshan District,
   Shen Zhen City, Guangdong Province, China.
   Contact person: *Pearl Chen*
   Contact Information: *Fax No:+86-0755-8993-6600; E-mail: yulong89@126.com*

2. Date summary prepared: November 10, 2010

3. Device Name:
   - Classification name: *Thermometer, Electronic, Clinical*
   - Classification number: *FLL, Class II*
   - Regulation Name: *880.2910*
   - Proprietary name: *Yu Long Sheng Disposable Thermometer Sheath*
   - Common Name: *Disposable Thermometer Sheaths*
   - Model: *YLS-01 for digital thermometer*
   - Predicate Device: *GOOD MEDY Disposable Thermometer Sheaths, K061007*

4. Indications for Use:
   YLS-01 disposable thermometer sheath is intended for use as a barrier that is used as an accessory to oral or rectal for digital thermometers. This thermometer sheath is non-sterile and is intended for single patient use only.

5. Description of the device:
   The Yu Long Sheng Disposable Thermometer Sheath(model YLS-01) is a plastic covering used for oral/rectal digital thermometer. This device is not made with natural rubber latex

6. Summary of the non-clinical testing data included in the submission :
   i. Material safety test conducted by SGS.
   ii. ISO10993-5 and ISO10993-10 biocompatibility test conducted by SUPERLAB.
   iii. ASTM E1104:03 product characteristics test conducted by Wincent Consultant.

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7. Legally marketed device for substantial equivalence comparison:
GOOD MEDY Disposable Thermometer Sheaths, K061007.

8. Comparison information
As the following comparison table.

Comparison feature	Model	
	Yu Long Sheng YLS-01	Good Medy (K061007)
Device Name	Yu Long Sheng Disposable Thermometer Sheaths	Good Medy Disposable Thermometer Sheaths
Indication for use	Use as a barriers that is used as an accessory to oral or rectal for digital thermometer	Use as a barriers that is used as an accessory to oral or rectal for digital thermometer
Construction	EVA film with upper and Lower exterior protection paper.	EVA film with upper and Lower exterior protection paper.
Use type	For single use	For single use
Size of single piece	94 x 26 mm	124 x 34 mm
Package	50 pcs in one packaging unit	1000 pcs in one packaging unit
Sterile package	Non-sterile package	Non-sterile package
Test Data	1. Material safety test. 2. Biocompatibility test according to ISO10993-5 & ISO10993-10. 3. Performance test according to ASTM E1104:98(2003).	1. Material Safety test. 2. Biocompatibility test according to ISO 10993-5 & ISO10993-10.

9. Summary for substantial equivalence comparison:

The new devices, Yu Long Sheng Disposable Thermometer Sheath, model YLS-01 for digital thermometer is substantially equivalent to the predicate devices: GOOD MEDY Disposable Thermometer Sheaths, K061007. The intended use of the two devices is the same, and the overall dimensions are similar. The two devices also had passed the biocompatibility test by ISO10993, same non-sterile and not made with natural rubber latex. Thus the new devices are substantially equivalent to the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Yu Long Sheng Technology Company, Limited
C/O Mr. Tony C. Chang
Wincent Consultant Company, Limited
No. 15, Alley 71, Chenping 1st
Beitun District
Taichung China (Taiwan) 406

JAN 10 2011

Re: K102508
Trade/Device Name: Yu Long Shen Disposable Thermometer Sheath/Model YLS-01
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 17, 2010
Received: December 20, 2010

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications For Use

JAN 10 2011

510(k) Number (if known): K102508

Device Name: Yu Long Sheng Disposable Thermometer Sheath / Model YLS-01

Indications For Use:

YLS-01 is intended for use as a barrier that is used as an accessory to oral or rectal for digital thermometers. This sheath is non-sterile and is intended for single patient use only.

Prescription Use _____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ACTING FOR RICHARD CHAPMAN
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102508